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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,223	08/12/1999	GEORG KALLMEYER	P8341-9011	5876

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EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/308,223	Applicant(s) KALLMEYER ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 and 15-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,36 and 115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *17* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Upon review, and reconsideration (see also Interview Summary attached), the Final Rejection (Paper No. 12) is hereby withdrawn.

The Amendment filed October 10, 2001 (Paper No. 14) in response to the Office Action of May 15, 2001 is acknowledged and has been entered. Claim 14 was cancelled. Claims 13,15-36 are pending and are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-26, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 15-26, 36 are indefinite for reciting "essentially free". The phrase essentially free is not defined by the claims, and the specification does not provide a standard for ascertaining what amount is considered essentially free and what amount is not. Hence one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13, 15-21, 23-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Andya *et al.* (US Patent No. 6,267,958, March 1996).

Andya *et al.* teach a variety of lyophilizates comprising monoclonal or polyclonal antibodies, sugars, amino acids, and surfactants wherein the lyophilizate is essentially free of polyethylene glycols and additional proteins; wherein the lyophilizate contains a single amino acid or two different amino acids; wherein the lyophilizate further comprises a buffering agent or an isotonizing agent which is present in an amount such that a reconstituted solution of the lyophilizate has a pH value of 5-8 (columns 3-5); wherein the lyophilizate is storage-stable for a time period of at least three months at a temperature of about 4-12^{0}C (column 8, lines 45+, columns 3-5); wherein the sugar comprises at least one member selected from the group

consisting of a monosaccharide, a disaccharide and a trisaccharide (column 15 line 12); wherein the sugar comprises sucrose or trehalose; wherein the amino acid comprises histidine, glutamic acid; wherein the surfactant comprises a polysorbate (column 15); wherein the monoclonal or the polyclonal antibody is directed against an antigen selected from the group consisting of integrins and or other antigens (column 7). Andya *et al.* further teach a variety of lyophilizates comprising monoclonal or polyclonal antibodies, sugars, amino acids, and surfactants, and an inorganic acid as a buffering agent (column 9, line 44); wherein the lyophilzate is dissolved in a physiologically acceptable solution; has a pH of 5-8; contains 1-10mg/ml of antibody (column 17). Andya *et al.* broadly anticipate a method of preparing a lyophilizate comprising mixing a buffered solution containing a monoclonal antibody or polyclonal antibody, a sugar, at least one amino acid and a surfactant, to prepare a mixed solution, wherein the mixed solution has a pH value of 5-8; and lyophilizing the mixed solution, wherein the lyophilizate is essentially free of polyethylene glycols and additional proteins. Further the molar concentrations of sugars, amino acids, and surfactants as claimed in claims 31-33 are also anticipated by Andya *et al.* (see columns 3-5). Although Andya *et al.* do not specifically teach that the lyophilizate is storage-stable for a time period of at least three months at a temperature of about 18-23^{0}C (Claim 18), the claimed lyophilizate appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable

differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 15-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andya *et al.* (US Patent No. 6,267,958, March 1996) in view of Michaelis *et al.* (US Patent No. 5,919,443, June 1995).

Andya *et al.* teach as set forth above.

Andya *et al.* do not include the teachings of an amino sugar such as glucosamine, N-methyl-glucosamine, galactosamine, and neuraminic acid.

Michaelis *et al.* teach the advantages of an improved lyophilizate which contains amino sugars (column 4,lines 1-6)

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to modify the lyophilizate of Andya *et al.* so as to include an amino sugar as taught by Michaelis *et al.* One would have been motivated to do so because Michaelis *et al.* make the surprising discovery that it is possible to produce stable forms of pharmaceutical agents when maltose, raffinose, sucrose, trehalose or amino sugars are used as additives (column 3, line 9). Michaelis *et al.* further teach that solid preparations which contain maltose, raffinose, sucrose, trehalose or amino sugars as auxiliary agents can be frozen or even stored at increased temperatures with no significant loss of protein quality. Hence, the teachings of Michaelis *et al.* suggest an improved and more versatile lyophilizate which can also contain amino sugar.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 13, 2001